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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,341	04/22/2005	Kurt Frimann Berg	BERG3	1525
1444 7590 10/11/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER SOLOLA, TAOFIQ A	
			ART UNIT 1625	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,341

Applicant(s)

BERG, KURT FRIMANN

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-27, 58-71, 74-78 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) 58-71, 74-78 and 81-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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Claims 1-27, 58-71, 74-78, 81-83 are pending in this application.

Claims 28-57, 72-73, 79-80 are cancelled.

DETAILED ACTION

Election/Restriction

Claims 1-27, 58-71, 74-78, 81-83 are drawn to more than one inventive concept (as defined by PCT Rule 13) and, accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that "special technical features" mean those technical features which, as a whole, define a contribution over the prior art (novelty/unobviousness).

- I. Claims 1-27, drawn to compositions, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.
- II. Claims 58-71, 74-78, 81-83, drawn to methods of using compositions of group I, classifiable in several non-heterocyclic classes (514, 558, 562, etc.), numerous subclasses.

In the instant inventions, the only structural elements shared by groups I-II are flavonoid and menthol, the elements of the compositions. However, flavonoid and menthol are well known in the art and composition comprising them is known. See WO/02/09699 in the International Search Report. Therefore, under PCT Rules 13.1 and 13.2, compositions comprising flavonoid and menthol do not constitute a corresponding special technical feature among the groups.

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If applicant elects the invention of group II or in a rejoinder thereof applicant must elect a specific disease and the elected invention would be examined commensurate in scope therewith.

In a telephone call made to Iver Cooper on 7/10/07, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

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Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

Response to Restriction

The election of group I, claims 1-27, with traverse in the Paper filed 9/20/07 is hereby acknowledged. The traversal is on the basis that the instant application is a 371 of a PCT and the restriction should have been based on PCT Rules. Therefore, Applicant asked for a new restriction based on PCT Rule and that if the groups are the same as in the restriction mailed 7/27/07, the election of group I be treated as response to the new restriction requirement. Therefore, the invention of group I is been examined as elected by applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims improperly depend from 1 and 3, respectively, for failure to limit the scope of 1 and 3. Claims 1-4 are drawn to a composition comprising the same constituents including a

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"pharmaceutically acceptable excipients". Claims 2 and 4 recite the inherent property of a "pharmaceutically acceptable excipients". Under the US patent practice, duplicate or substantially duplicate claims cannot be in the same application. By deleting claims 2, 4, the rejection would be overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al., WO 02/09699.

Applicant claims compositions comprising purified flavonoids and purified menthol. In preferred embodiments the compositions comprise different flavonoids derivatives such as troxerutin and veneruton, further comprise zinc metal complex/salts, and compositions essentially free of one/more of menthone, methyl acetate, limonene and neomenthol. Some of these are minor constituents of peppermint oil, which are not known or shown in the specification to be injurious. The major constituent of peppermint oil is menthol. The term "essentially free" implies the compositions are not 100 % free of the listed compounds

Determination of the scope and content of the prior art (MPEP 2141.01)

Berg et al., teach compositions comprising purified flavonoids and zinc metals complex/salts and optionally peppermint oil. The zinc metals are the same as in the instant invention and the compositions may comprise different flavonoids derivatives such as troxerutin and veneruton. See page 5, paragraph 7 to page p, paragraph 3.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Berg et al., is the level of purities of menthol in the compositions.

Finding of prima facie obviousness—rational and motivation (MPEP 2142.2413)

However, changing the level of purity of menthol is an obvious modification available to the preference of an artisan, and does not rise to the level of invention under the US patent practice. It is a mere optimization of a variable, which is not patentable absent unexpected result due to the variable, which is different in kind and not merely in degree from that of the prior art. *In re Aller*, 22 F.2d 454, 105 USPQ 233 (CCPA, 1955). Therefore, the instant invention is prima facie obvious from the teaching of Berg et al. One of ordinary skill in the art would have known to change the levels of purities of menthol at the time this invention was made. The motivation is to obtain a purer composition.

Alternatively, none of the flavonoids, zinc metal complex/salts and menthol is applicant's invention. They are in the public domain prior to the time the instant invention was made. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done (mode of action) separately. *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra*. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra*.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1625

October 6, 2007